Bazaral, Michael G.
From: Weitershausen, Joanna
Sent: Tuesday, June 05, 2001 7:40 AM
To: 'AlexSMCCC@aol.com'
Cc: Bazaral, Michael G.; Noe, William A
Subject: FW: Panel meeting

Alex, attached are materials we think should be sent to the panel. Item 6 lists information that needs to be provided as an amendment.

Please except my apology for the delay in sending this email message.

Thank you,

Joanna H. Weitershausen

-----Original Message-----
From: **Bazaral, Michael G.**
Sent: Monday, June 04, 2001 2:27 PM
To: Weitershausen, Joanna
Subject: RE: Panel meeting

Mr. Stenzler:

1) list of the PMA material (page or section numbers) we think should be sent to the panel

HFOV list PMA 1st.doc

2) text of the preliminary FDA clinical review

HFOV clinical 1st.doc

3) text of the preliminary FDA engineering review

HFOV Engineer 1st.doc

4) text of the preliminary FDA statistical review

HFOV statistics 1st.doc

5) a list of published reprints that will be sent to the panel

HFOV Refs 1st.doc

6) request for additional information that we think you should provide; that information would be an amendment to this supplement

HFOV quest sensorm 1st.doc

7) a list of the FDA questions for the panel that are developed as of the date of the E-mail

HFOV pan quest 1st.doc

This will be followed by a printed copy to you.

By June 11 or so, we will need to have in E-mail from you:
a) agreement or comment on PMA material to be sent by the FDA to the panel as identified in 1 above
b) additional information as requested by the FDA in 6 above
c) any other information you think the panel should have.

By June 13 we will need the actual PMA material, additional information as requested by the FDA, and any other information from you in printed physical form as a "sponsor's panel pack".

Copies of these items will be sent to the panel as the "sponsors panel package"; this material will also be sent to our Freedom Of Information Office for review. You will be asked to interact with the Freedom of Information of Information (FOI) office regarding what information will be not made public before the meeting (patient identity or proprietary information). On the basis of our discussion I expect that little or none of your material will be need to be redacted

The FDA will send to the panel concurrently as the "CDRH Background"
d) text of the preliminary clinical review
e) text of the preliminary engineering review
f) text of the preliminary statistical review
g) reference material such as reprints of pubished material etc, corresponding to 5 above.
h) a list of the FDA questions for the panel that are developed (as of the date of the E-mail June 4)

Also if you have comments or want to discuss any of this during early June, please call me 301 443 8609x140 or Bill Noe x174

We expect to sent by Fedex from the FDA to the panel members all of the above on about June 15, leaving then 4 weeks to the meeting.

We will complete reviews from the FDA relative to the additional material from you and other considerations, and the draft of updated FDA questions, and will send you E-mail copies by June 21 or so (followed by a printed copy). We will await your comments that you may want to send to the panel. Our updated reviews, questions, and your comments or additional material will be sent to the panel Fedex, and to FOI by June 29. After that, no additional review material will be sent to the panel.

All the material, except what might be redacted, will be posted on the FDA web site for public view July 13, and will also be available in the dockets management office.

The above corresponds as far as I know with the current policy. If that is not OK by you let me know and we can discuss how to cope. But also I may learn that the policy is not exactly as I thought, so the above plan might be modified a bit. The open session for your product will be from noon to 5 pm July 16. Do plan on at least 1/2 or up to one hour for a presentation to the panel. Except for answers to questions from the panel, no data or analysis that has not been sent as part of the PMA or as part of the additional information provided for the panel packs should be included in your presentation.

Mike Bazaral